REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application, in light of the following remarks, is respectfully requested.

By the present amendment, Claim 20 has been amended and Claim 23 has been cancelled. Claims 24 and 25 have been amended to correct dependency in light of the incorporation of the recitation of Claim 23 in Claim 20. No new matter enters by this Amendment.

REJECTIONS OF CLAIMS 20-26 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 20-26 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

The Examiner's rejection is premised on the Examiner's conclusion that:

> Applicant has not proven how this partial inhibition of HIV or Ebola *in vitro* by anti-TGS101 (SIC, TSG101) antibodies can result in clinical benefit *in vivo,* particularly when the other partially un-inhibited viruses can continue to replicate *in vivo*.

Office Action, page 5, item 14. Fundamentally, the Examiner's rejection is premised on the absence of *in vivo* results. See also, paragraph 17.

Respectfully, the Examiner has miscategorized the burden on Applicant. Proof of effectiveness is not required. Scientifically sound explanations, backed by *in vitro* testing, are widely accepted as sufficient evidence to support claims drawn to subject matter commensurate in scope with that support. See, *In re Brana*, 51 F.3rd 1560, 34 USPQ 2nd 1436, 1441 (Fed. Cir. 1995) where the Court specifically rejected the Examiner's formulation herein. Specifically, the Court held that it was not incumbent on Applicant to prove utility, and that rather, challenge fell to the Patent Office unless there is reason to doubt the objective truth of the statements of the specification. The Examiner's standard applied was specifically rejected by the Court at 1442-1443:

> Were we to require phase 2 testing in order to prove utility, the associated cost would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer. 34 USPQ 2nd at 1442-1443.

The rejection is respectfully traversed.

Moreover, Applicant respectfully submits that upon the introduction of the above amendments, the factors identified by the Examiner work in favor of Applicant. The nature of the invention is treatment (not prevention or eradication) of a virus. This is hardly an incredible concept. The claims have been limited to antibodies having an

epitope in a very specific narrow range, whose effectiveness in inhibiting viral budding and production is acknowledged in the Office Action, page 13.

The remaining factors considered by the Examiner, since the Examiner concedes the presence of working examples and guidance, is the degree of predictability in the art, that is, would *in vivo* testing follow, without undue experimentation, the promise of *in vitro* testing. The Examiner relies on a general observation that "the prior art has described that most antibody therapy for treating viral infections provides no benefit due to lack of effective antibodies and 'other obstacles' to maintain an effective concentration of antibody *in vivo*, failing to compete with viral replication." Office Action, page 5. Respectfully, the Examiner is comparing apples and oranges. Applicant's technology rests on the identification of a critical protein involved in budding, and provides antibodies which, in addition to inhibiting budding and thus viral proliferation, effects lysis of infected cells to which the antibody is bound. See the specification, page 28, lines 8-15.

Again, Applicant notes that the statements and evidence in the specification must be accepted in the absence of a reasonable basis for disbelieving them. Analogizing the claimed invention to other technology, where the antibody is used only as an antagonist, which is the type of treatment characterized in the Office Action, as opposed to

Applicant's claims, is not a reasonable basis for rejecting the claims for lack of enablement.

A final observation is of importance. The claims are directed to treatment of viral infection. They do not call for prevention, they do not call for eradication. They call for treatment. The Examiner is critical of the effectiveness of antibodies that retard 70% or better of viral particle production. It is respectfully submitted that a human infected with HIV would regard a 70% retardation of viral particle production as a useful result. Better results are described, and even better efficiency can be achieved through routine testing and selection. Even at a 70% inhibition rate, this is a profound and important contribution. Retarding the course and speed of a virus is frequently the first and most important step in treating an infection.

Given the amendments advanced, the Examiner is respectfully requested to reconsider and withdraw the rejection for enablement. Should the Examiner elect to persist in the rejection, the Examiner is invited to specifically identify what type or character of undue experimentation would be required to practice the invention. The antibodies of the invention are drawn against a narrow range of epitopes. The viruses against which the antibodies are effective are familiar and specifically called out in the specification. Protocols for the *in vivo* testing of antibodies shown to be effective *in vitro* are well established. The fact that deployment of an invention requires a good deal of

testing should not be equated with undue testing. See the citation relied on by the Examiner *In re Wands*, 8 USPQ 2nd 1400, 1406-1407 (Fed. Cir. 1998). Respectfully, Applicant has provided sufficient guidance, sufficient information, and sufficient incentive to guide those of skill in the art, who the Examiner omitted to observe, as compelled in *Wands*, are of the very highest skill level possible, to practice the claimed invention without undue experimentation. That the steps of clinical testing remain to be completed does not detract from this conclusion. Withdrawal of the rejection is respectfully requested.

REJECTIONS OF CLAIMS 20-22 AND 25 UNDER 35 U.S.C. § 102(E)

Claims 20-22 and 25 stand rejected under 35 U.S.C. § 102(e) as purportedly being anticipated by U.S. Patent Application Publication No. 2004/0109861 (**Zavitz**). This rejection is mooted by the amendments presented herein. Further, Applicant notes that **Zavitz** is not prior art to Applicant. The publication takes a presumptive date under 35 U.S.C. § 102(e) as of the time the complete published disclosure was filed – in this case 2003. Applicant is entitled to an effective filing date of 2002. Withdrawal is respectfully requested.

CONCLUSION

All outstanding issues have been resolved by amendment or otherwise overcome by argument. As the claims are in condition for allowance an early and favorable action thereon is respectfully requested. If the Examiner believes a telephone conference could advance prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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